

PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY

RECEIVED 12 JAN 2005

To:

Halford & Co.
No 1 Market Street
SYDNEY NSW 2000

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year)	12 JAN 2005
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Applicant's or agent's file reference
C04127

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/AU2004/001420

International filing date (day/month/year)
15 October 2004

Priority date (day/month/year)
17 October 2003

International Patent Classification (IPC) or both national classification and IPC
Int. Cl. ⁷ A61M 16/00

Applicant

RESMED LIMITED et al

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input checked="" type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the IPEA/AU
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Box No. I **Basis of the opinion**

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:

☒ paid additional fees

☐ paid additional fees under protest

☐ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

☐ complied with

☒ not complied with for the following reasons:

This International Searching Authority found multiple inventions in this international application as follows:

Claims 1-46 relate to a method and apparatus for detecting reflex vocal cord closure

Claims 47-67 relate to a method and apparatus for assessing treatment by determining heart treatment index as a function of duration and pressure of gas delivery

Claims 68-91 relate to a method and apparatus for treating heart failure by generating a cardiac pressure waveform synchronized with the cardiac rhythm of the patient

Claims 92-178 relate to a method and apparatus for evaluating heart failure from the airflow of the patient

Since the only feature held in common by all of the claims is the delivery of controlled above atmospheric pressure gas to the patient which is common to all CPAP treatment, a lack of unity exists a posteriori.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

☒ all parts

☐ the parts relating to claims Nos.

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**WRITTEN OPINION OF THE
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International application No.

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Box No. V **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	<p>Claims 9, 10, 12, 14, 16, 18, 25, 29, 31-33, 37, 38, 40, 42, 44-46, 53, 60, 67, 71-75, 79-83, 87-91, 95, 98, 99, 105-115, 117, 119-120, 124, 127, 128, 130, 134-144, 146, 148, 149, 153, 156, 157, 159, 163-173, 175, 177, 178</p> <p>Claims 1-8, 11, 13, 15, 17, 19-24, 26-28, 30, 34-36, 39, 41, 43, 47-52, 54-59, 61-66, 68-70, 76-78, 84-86, 92-94, 96, 97, 100-104, 116, 118, 121-123, 125, 126, 129, 131-133, 145, 147, 150-152, 154, 155, 158, 160-162, 174, 176</p>	<p>YES</p> <p>NO</p>
Inventive step (IS)	<p>Claims 9, 10, 12, 14, 16, 18, 25, 29, 31-33, 37, 38, 40, 42, 44-46, 53, 60, 67, 71-75, 79-83, 87-91, 95, 98, 99, 105-115, 117, 119-120, 124, 127, 128, 130, 134-144, 146, 148, 149, 153, 156, 157, 159, 163-173, 175, 177, 178</p> <p>Claims 1-8, 11, 13, 15, 17, 19-24, 26-28, 30, 34-36, 39, 41, 43, 47-52, 54-59, 61-66, 68-70, 76-78, 84-86, 92-94, 96, 97, 100-104, 116, 118, 121-123, 125, 126, 129, 131-133, 145, 147, 150-152, 154, 155, 158, 160-162, 174, 176</p>	<p>YES</p> <p>NO</p>
Industrial applicability (IA)	<p>Claims 1-178</p> <p>Claims</p>	<p>YES</p> <p>NO</p>

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2. Citations and explanations:

D1 GB 2294642

D4 WO 1989/009041

D7 US 5188098

D10 US 2003/0121519

D13 US 5794615

D2 WO 2000/067827

D5 US 2002/0169384

D8 WO 2002/026283

D11 EP 1295623

D3 US 5353788

D6 WO 1997/030744

D9 WO 1999/061088

D12 WO 1999/045989

NOVELTY (N) Claims 1-8, 11, 13, 15, 17, 19-24, 26-28, 30, 34-36, 39, 41, 43, 47-52, 54-59, 61-66, 68-70, 76-78, 84-86, 92-94, 96, 97, 100-104, 116, 118, 121-123, 125, 126, 129, 131-133, 145, 147, 150-152, 154, 155, 158, 160-162, 174, 176

Claims 1-8, 11, 13, 15, 17, 19-24, 26-28, 30, 34-36, 39, 41, 43,

The features of each of the above listed claims are provided by GB 2294642. For example the features of claim 1 are provided as follows:

Delivering a controlled supply of above atmospheric pressure gas to patient

Page 1

Deriving measure indicative of vocal cord closure

Pages 2 and 5-7

Detecting incident of vocal cord closure as function of said measure

Pages 2 and 5-7

Claims 47, 49-52, 54-59, 61-66 - All the features of each of these claims are provided by D2 similarly to the above. All the features of each of claims 47, 54 and 61 are also provided by each of D3, D4 and D5. All the features of each of claims 49, 55, 56, 62 and 63 are also provided by D5.

Claim 48 - All the features of claim 48 are provided by D5.

Claims 68, 76, 84 - All the features of each of these claims are provided by D4, D6 and D7.

Claims 69, 70, 77, 78, 85, 86 - All the features of each of these claims are provided by D4.

Claims 92, 121, 150 - All the features of each of these claims are provided by D2, D8, D9, D10, D11, D12, and D13

Claims 93, 122, and 151 - All the features of each of these claims are provided by D8, D9 and D11

Claims 94, 96, 123, 125, 126, 152, 154, 155, - All the features of each of these claims are provided by D2, D8 and D9

Claim 97 - All the features of this claim are provided by D2 and D8

Claims 100, 103, 116, 129, 145, 158, 174 - All the features of each of these claims are provided by D8 and D9

Claims 101, 102 - All the features of each of these claims are provided by D9

Claims 104, 118, 131-133, 147, 160-162, 176 - All the features of each of these claims are provided by D8

INVENTIVE STEP (IS) Claims 1-8, 11, 13, 15, 17, 19-24, 26-28, 30, 34-36, 39, 41, 43, 47-52, 54-59, 61-66, 68-70, 76-78, 84-86, 92-94, 96, 97, 100-104, 116, 118, 121-123, 125, 126, 129, 131-133, 145, 147, 150-152, 154, 155, 158, 160-162, 174, 176

Since these claims lack novelty, they also lack inventive step.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 52, 59 and 66 are not clear because there is no antecedent to the words "said amplitude".

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